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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/770,535	Applicant(s) HAMILTON, NATHAN D.	
	Examiner Brian-Yong S Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

Claims 2, 7 and 12 are objected to because of the following informalities: Abbreviation of word "ALC" should be spelled out as "acetyl-L-carnitine". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for carbohydrate, protein or fat, does not reasonably provide enablement for the term "at least one energy source" . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404* where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman, 230 USPQ 546 (BdApls) at 547* the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that define those characteristics defining "at least one energy source". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain what is "at least one energy source" without undue experimentation. Furthermore, the specification fails to provide sufficient working examples. It is noted that theses examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all or any agent that could generate energy, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-7, 9-12 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite and unclear by reciting "a suitable antioxidant" and the specification does not define the term. The specification discloses (in page 3, lines 17-24) that "mitochondrially active antioxidants including vitamins (especially C, E, B and D)...". Does applicant refer to those antioxidants (in page 3, lines 17-24 of the instant specification)? Applicant is requested to clarify.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sole et al. (US 6232346 B1) in view of Ames et al. (US 5916912 A) and admitted prior arts (page 2, lines 3-22).

The claims read on a pet food composition comprising an antioxidant, a carnitine, carbohydrate, protein, fat and fiber. Further limitations include ALC as the carnitine in the amount of about 0.1 grams to 3 grams in claim 2; R-alpha-lipoic acid as the antioxidant in the amount of 0.1 grams to 1.5 grams in claim 3; and coenzyme Q and creatine as the additional ingredients in claim 4 and 5 respectively.

Sole teaches a dietary supplement (for mammals including dog and cat) comprising L-carnitine (or its functional analogues such as acetyl-carnitine or proprionyl-l-carnitine), coenzyme Q10, creatine, antioxidants (e.g., vitamin E, Vitamin C), carbohyrate, fat and protein (Fig. 6A-6B). Solo discloses that "carnitine improves mitochondrial DNA transption and translation in aged animals". Ames teaches the combination use of acetyl-L-carnitine and antioxidant such as lipoic acid to rejuvenate the mitochondria in aging animals (column 1, lines 36-47). Ames also teaches that "methods for making and preparing carnitine and active carnitine derivatives are known in the art...For example, lipoic acid derivatives and their methods of production are well described..." (column 2, line 34 thru column 3, line 7).

Admitted prior art of records discloses various pet food formulations containing protein, fat, carbohydrate, crude fiber and vitamins.

The teaching of Sole differs from the claimed invention in the use of R-alpha-lipoic acid in combination with carnitine containing pet food formulation. To incorporate such teaching into the teaching of Sole, would have been obvious in view of Ames who teaches the combination

use of acetyl-L-carnitine and lipoic acid to increase the metabolic rate of aged cells in older animals and Admitted prior art of records that discloses various commercially available pet food formulations containing protein, fat, carbohydrate, crude fiber and vitamins.

Above references in combination make clear that the combination use of acetyl-L-carnitine and antioxidant such as lipoic acid to rejuvenate the mitochondria in aging animals or increase the metabolic rate of aged cells in older animals is old and well known. Above references in combination also make clear that the use of coenzyme Q10 and creatine in pet food formulations containing protein, fat, carbohydrate, fiber and vitamins are old and well known. One having ordinary skill in the art would have been motivated to modify the teaching of Sole such that the enhanced anti-aging pet composition could be formulated. One having ordinary skill in the art would have expected that the addition of lipoic acid to the Sole's pet composition containing carnitine (e.g., L-carnitine or acetyl-L-carnitine) further enhance mitochondrial functions and reverse several gross indicia of aging, including activity, muscle tone, coat appearance and kidney morphology, as taught by Ames (column 1, lines 36-47). Furthermore, one having ordinary skill in the art would have known that the employment of R-alpha-lipoic acid in said pet formulation is well within the skill of the artisan, as taught by Ames (column 3, lines 7).

Additionally, the optimization of amounts of known active and inactive ingredients in a composition is well considered within the skill of the artisan, absent evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600